K112440

AB DENTAL SUMMARY

APR 18 2012

Company

AB Dental Devices Ltd.
3 Habosem St, Ashdod
Israel
Telephone: (+972) 8-853-1388
Fax: (+972) 8-8522262
FDA Establishment Registration # 3005663340

Contact

Dr. Charles Hurwitz
Regulatory Consultant
MedicSense Ltd
POB 367
Ramat Hasharon 47103
Israel
Phone: +972 3 9233666
Fax: +972 3 9231274
Email: charles@medicsense.com

Classification Name

Per 21 CFR 872.3640

- Endosseous Dental Implants and Accessories Product Code DZE
- Abutment, Implant, Dental Endosseous. Product Code NHA

Device Description

AB Dental implants are designed to support prosthetic devices in edentulous or partially edentulous patients to restore esthetics and chewing functions.

The purpose of this submission is to add new implants, abutments and other items and to receive approval for a new surface treatment to previously-approved implants.

Indications for Use

The AB Dental Devices implants are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

I7 Integral implant, I5 Conical implant, P15 Temporary abutment, P12-T,L Temporary flat connection abutment, and P16 Straight adaptor are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Identification of the Legally Marketed Predicate Devices Used to Claim Substantial Equivalence

The following predicate devices are cited:

AB Dental Product	Predicate and K number	Predicate and K number
I2 Screw Type	AB Dental I2, screw type, K051719	M.I.S Implant Technologies, Bio-Com, K040807
I5 Conical	AB Dental, I5 Conical, K051719	M.I.S Implant Technologies, Lance, K040807
I7 Integral	AB Dental, I7 One-piece, K051719	M.I.S Implant Technologies, Uno one piece screw type, K080162
I10 Trapeze	Nobel Biocare, Nobel Active, K102436	ADIN, Touareg WP5mmD, K081751
P1-Non Hexed Abutment	AB Dental, P1-Non Hexed Abutment, K051719	Biohorizon, Titanium Temporary Abutments - Non-hexed, K103691
P3 Abutment Anti-rotation	AB Dental, P3 Abutment Anti-rotation, K051719	Biohorizon, Internal Laser-Lok Abutment, K103691
P3N-Narrow Anti-rotation Abutment	AB Dental, P3 Narrow Abutment Anti-rotation, K051719	MIS, MN-MAC10, Narrow platform cementing post, NP, K040807
P3W – Wide anti-rotation abutment	MIS, MD-WMAC1 Wide cementing post, SP, K040807	AlfaBio tec, TLAW, K063364
P3W – Wide anti-rotation abutment	MIS, MD-WMAC1 Wide cementing post, SP, K040807	AlfaBio tec, TLAW, K063364
P9HG-3.75,11 Gold Composed Hex Abutment	AlfaBio tec, TLABG, K063364	MIS, MG-GPC10 Direct gold plastic cylinder with hex. Internal hex, K063364
P12-3.75 - Flat Connection Abutment	Adin, FC-6013,6018, K081751	
P12-3.75-T - Temporary Flat Connection Abutment	Adin, FC-6013,6018, K081751	
P15-3x - Temporary Abutment for Immediate Loading	Alpha-Bio Tec, Straight Titanium Abutments ETLA, K063364	
PO-P6H for Aesthetic Abutment with Hex	Alpha Bio, HCT, K042654	
PO-Titanium Healing Cap	Alpha Bio, HS, K042654	Adin, WP-0046,0047,0048,0049,0050, K081751
P16-Straight adaptor	MIS, Pilier Multi Unit, K040807	

	Current	*Predicate*	*Predicate*
IMPLANTS			
	AB Dental	***AB Dental***	***M.I.S Implant Technologies***
Product Name	I2 Screw Type	I2 Screw Type	Bio-Com
K Number		K051719	K040807
Placement Method	Dual-step surgery. Later exposure required.	Dual-step surgery. Later exposure required.	Dual-step surgery. Later exposure required.
Indication for Use	For use in dense bone	For use in dense bone	For use in dense bone
Length(s)	8,10,11.5,13,16, 18,20	8,10,11.5,13,16,18 ,20	8,10,11.5,13,16
Available diameters (mm)	3.25,3.75,4.2,4.5 ,5,6	3.25,3.75,4.2,4.5,5 ,6	3.3,3.75,4.2,4.7
Integrated Abutment	No	No	No
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy. Grade-4.
External Surface	Sandblasted and acid etched surface .(HA)	Sandblasted and acid etched surface (SLA).	Sandblasted and acid etched surface (SLA).
Self Tapping	Yes	Yes	Yes
	AB Dental	***AB Dental***	***M.I.S Implant Technologies***
Product Name	I5 Conical	I5 Conical	Lance
K Number		K051719	K040807
Placement Method	Dual-step surgery. Later exposure required.	Dual-step surgery. Later exposure required.	Dual-step surgery. Later exposure required.
Indication for Use	Used in soft bone and designed to enable the change of direction during implantation.	Used in soft bone and designed to enable the change of direction during implantation.	Used in soft bone
Length	8,10,11.5,13,16	8,10,11.5,13,16	10,11.5, 13,16
Available	3,3.2,3.75,4.2,4.	3.2,3.75,4.2,4.5,5,	3.75,4.2,5

diameters (mm)	5.	6	
Integrated Abutment	No	No	No
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy. Grade-4.
External Surface	Sandblasted and acid etched surface.(HA)	Sandblasted and acid etched surface (SLA).	Sandblasted and acid etched surface (SLA).
Self Tapping	Yes	Yes	Yes
	AB Dental	***AB Dental***	***M.I.S Implant Technologies***
Product Name	I7 Integral	One-piece I7	UNO - ONE PIECE SCREW-TYPE
K Number		K051719	K080162
Placement Method	Single-step surgery. No exposure required.	Single-step surgery. No exposure required.	Single-step surgery. No exposure required.
Indication for Use	For immediate loading.	For immediate loading.	For immediate loading.
Length	10,11.5,13,16	10,11.5, 13,16	10,11.5, 13,16
Available diameters (mm)	10,11.5,13,16	10,11.5, 13,16	3,3.5
Integrated Abutment	Yes	Yes	Yes
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy Ti-6Al-4V-ELI. Grade-5.
External Surface	Sandblasted and acid etched surface.(HA)	Sandblasted and acid etched surface (SLA).	Sandblasted and acid etched surface (SLA).
Self Tapping	Yes	Yes	Yes
Pull out strength test (Newtons)	162.9N	------	135.8N
	AB Dental	***Nobel Biocare***	***ADIN***

Product Name	I10 Trapeze	Nobel Active	Touareg WP5mmD
K Number		K102436	K081751
Placement Method	Single-step surgery. No exposure required.	Single-step surgery. No exposure required.	Single-step surgery. No exposure required.
Indication for Use	Is suitable for all indications and offers exceptional primary stability. Designed to enable the change of direction during implantation.	Is suitable for all indications and offers exceptional primary stability.	Is suitable for all indications.
Length	8,10,11.5,13,16	8.5,10,11.5,13,16	8.5,10,11.5,13,15
Available diameters (mm)	3.75, 4.2, 5	4.3,5	5
Integrated Abutment	No	No	No
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium	Titanium alloy Ti-6Al-4V-ELI.
External Surface	Sandblasted and acid etched surface.(HA)	Anodized surface: partial crystalline and phosphate enriched titanium Oxide surface.	OsseoFix, Calcium phosphate treated surface.
Self Tapping	Yes	Yes	Yes
ABUTMENTS			
	AB Dental	***AB Dental***	***Biohorizon***
Product Name	P1-Non Hexed Abutment	P1-Non Hexed Abutment	Titanium Temporary Abutments - Non-hexed
K Number		K051719	K103691
Indication for Use	For connecting two or more implants by using a permanent rod. For permanent	For connecting two or more implants by using a permanent rod. For permanent and final	Use for multiple-unit, screw-retained, long term temporary restorations (>30 days).

	and final restoration.	restoration.	
Dimensions	Diameter:3.75 Length:9,13	Diameter:3.75 Length:9,13	Diameter:3.5,4.5,5.7 Length:12
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy
Angle	No	No	No
	AB Dental	***AB Dental***	***Biohorizon***
Product Name	P3 Abutment Anti-rotation	P3 Abutment Anti-rotation	Internal Laser-Lok Abutment
K Number		K051719	K103691
Indication for Use	When wide spaces are required, for back teeth. When space is limited, between two teeth or implants at the anterior of the mouth. For thick gums when the implant is very deep.	When wide spaces are required, for back teeth. When space is limited, between two teeth or implants at the anterior of the mouth. For thick gums when the implant is very deep.	Designed to be placed at implant surgery or uncover and remain in place through final restoration.
Dimensions	Diameter3,3.75, 5 Length:5,7,9,12, 15	Diameter:3.75 Length:5,7,9,12,15	Diameter:3.5,4.5,5.7Length:4,5.5
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium Alloy.
Angle	No	No	No
	AB Dental	***AB Dental***	***Zimmer***
Product Name	P3S Anatomic Anti-rotation	P3S Anatomic Anti-rotation	Hex-Lock Contour Abutment
K Number		K051719	K052600
Indication for Use	To follow the gum line.	To follow the gum line.	For limited interocclusal Space.
Dimensions	Diameter:3.75 Cuff Height:1,2,3.	Diameter:3.75 Cuff Height:2,3,4.	Diameter:3.5,4.5,5.7 Cuff Height:1,2,3.
Material	Titanium alloy	Titanium alloy Ti-	Titanium Alloy.

Indication for Use	To be used when space is limited, between two teeth or implants, usually at the anterior of the mouth.	To be used when space is limited, between two teeth or implants, usually at the anterior of the mouth.	To be used when space is limited, between two teeth or implants, usually at the anterior of the mouth.
Dimensions	Diameter:3.75 Length:5,7,9.	Diameter:3.75 Length:5,7,9.	Diameter:3.75 Length:11
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy
Angle	No	No	No
	AB Dental	**MIS**	**AlfaBio tec**
Product Name	P3W – Wide anti-rotation abutment	MD-WMAC1 Wide cementing post, SP	TLAW
K Number		K040807	K063364
Indication for Use	To be used when there is a wide space between two teeth or implants, usually at the posterior part of the mouth	To be used when there is a wide space between two teeth or implants, usually at the posterior part of the mouth	To be used when there is a wide space between two teeth or implants, usually at the posterior part of the mouth
Dimensions	Diameter: 3.75 Length: 9, 12.	Diameter: 5.5 Length:11	Diameter: 4.5 Length:9
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium	Titanium
Angle	0	0	0
	AB Dental	**Adin**	

	Ti-6Al-4V-ELI. Grade-5.	6Al-4V-ELI. Grade-5.	
Angle	No	No	No
	AB Dental	***AB Dental***	***MIS***
Product Name	P3N-Narrow Anti-rotation Abutment	P3N-Narrow Anti-rotation Abutment	MN-MAC10 Narrow platform cementing post. NP

Product Name	P12-3.75 - Flat Connection Abutment	FC-6013,6018	
K Number		K081751	
Indication for Use	Abutment with a flat connection for screw retained restoration on tilted implants	Abutment with a flat connection for screw retained restoration on tilted implants	
Dimensions	Diameter:4.5 Length:5	Diameter:4 Length:5	
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	
Angle	0	0	
	AB Dental	**Adin**	
Product Name	P12-3.75-T - Temporary Flat Connection Abutment	FC-6013,6018	
K Number		K081751	
Indication for Use	Temporary abutment with a flat connection for screw retained restoration on tilted implants	Abutment with a flat connection for screw retained restoration on tilted implants	
Dimensions	Diameter:4.5 Length:15	Diameter:4 Length:5	
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	Titanium alloy Ti-6Al-4V-ELI. Grade-5.	
Angle	0	0	
	AB Dental	***Alpha-Bio Tec***	
Product Name	P15-3x - Temporary Abutment for Immediate Loading	Straight Titanium Abutments ETLA	
K Number		K063364	
Indication	Used for	Used for	

for Use	temporary restoration.	temporary restoration.	
Dimensions	Diameter:3, 3.75 Length: 1,2,3,4,5,7	Diameter:3.9,4.5 Length: 7	
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5+plastic.	Titanium alloy Ti-6Al-4V-ELI. +plastic.	
Angle	0	0	
HEALING CAPS			
	AB Dental	***Alpha Bio***	
Product Name	PO-P6H for Aesthetic Abutment with Hex	HCT	
K Number		K042654	
Indication for Use	Used to allow the gingiva to heal around P6H abutment	Used to allow the gingiva to heal around P6H abutment	
Dimensions	Diameter:4.7 Length:5	Diameter:4.7 Length:5	
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5	Titanium alloy Ti-6Al-4V-ELI. Grade-5	
	AB Dental	***Alpha Bio***	**Adin**
Product Name	PO-Titanium Healing Cap	HS	WP-0046,0047,0048,0049,0050
K Number		K042654	K081751
Indication for Use	Used to allow the gingiva to heal around implants	Used to allow the gingiva to heal around implants	Used to allow the gingiva to heal around implants
Dimensions	Diameter:3.75 Length:2,3,4,5, 6,7	Diameter:4.5 Length:2,3,4,5,6,7	Diameter:4 Length:2,3,4,5,6
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5	Titanium	Titanium alloy Ti-6Al-4V-ELI. Grade-5
ADAPTORS			
	AB Dental	***MIS***	

Product Name	P16-Straight adaptor	Pilier Multi Unit	
K Number		K040807	
Indication for Use	Used for screw retained restoration	Used for temporary restoration	
Dimensions	Diameter:3.0,3.75 Length:1,2,3,4,5.	Diameter:3.75 Length:1,2,3,4	
Material	Titanium alloy Ti-6Al-4V-ELI. Grade-5	Titanium alloy Ti-6Al-4V-ELI.	

Brief Discussion of the Non-Clinical Tests Submitted

As part of demonstrating safety and effectiveness of AB Dental dental implants and in showing substantial equivalence to the predicate devices that are the subject of this 51 0(k) submission, AB Dental submitted a selected number of its dental implants for fatigue testing in accordance with ISO 14801, Dentistry - Implants - Dynamic Fatigue Test for Endosseous Dental Implants.

Further, AB Dental dental implants also underwent extensive SEM surface analysis and surface topography studies to prove that the blasting and post-blasting surface cleaning process used during the manufacture of these devices produced implants that resulted in a clean, textured, surface.

In addition, the I7 implants were subjected to pullout testing.

Clinical Testing

No clinical testing was performed. Non-clinical testing was used to support the decision of safety and effectiveness.

Conclusions

We believe that the AB Dental Implants products, which are the subject of this submission are substantially equivalent predicate devices cited. The device constitutes a safe, reliable and effective medical device, meeting all declared requirements of its intended use and the device does not introduce new risks and does not present any adverse health effects or safety risks to patients when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

A.B. Dental Devices, LTD
C/O Charles Hurwitz, Ph.D.
MedicSense LTD
POB 367
Ramat Hasharon
ISRAEL 47103

APR 18 2012

Re: K112440
Trade/Device Name: AB Dental Devices Implants and Accessories
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 10, 2012
Received: April 13, 2012

Dear Dr. Hurwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number K112440

Device Name: AB Dental Dental Devices Implants and Accessories

Indications For Use :
The AB Dental Devices implants are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.
I7 Integral implant, I5 Conical implant, P15 Temporary abutment, P12-T,L Temporary flat connection abutment, and P16 Straight adaptor are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE(

Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112440